

MEDICATION COMPLIANCE AND MANAGEMENT DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] Not Applicable

STATEMENT RE: FEDERALLY SPONSORED RESEARCH/DEVELOPMENT

[0002] Not Applicable

BACKGROUND OF THE INVENTION

[0003] The present invention relates generally to a medication dispensing method, and more particularly to a medication dispenser and to a method of aiding patients to remain compliant with a complicated pharmaceutical regimen by providing the patient with a quantity of medication dispensers, tracking the quantity of medication dispensers in possession of the patient, contacting a prescribing doctor to obtain authorization to refill additional medication dispensers, and delivering refilled medication dispensers to the patient.

[0004] In life, unfortunate conditions occur such that people become hospitalized and/or require medication. The medication needed may have to be taken over the course of a patient's lifetime or merely for a short interim period while the patient is recovering. In either case, the patient at times may be taking a plurality of different types of pills. The pills may have to be taken every day or every other day. Additionally, the pills may have to be taken at different intervals throughout the day on which they are taken. Perhaps, individually, each pill consumption requirement as to the day of the week and the time of day may be very simple and may be complied with by the patient through memory. However, if the patient must take more than a few different types of pills, then the consumption

requirement for the aggregate of all the pills increase a complexity of a pharmaceutical regimen.

[0005] At times, compliance with the pharmaceutical regimen may determine the survival of a person's life. In this regard, the patient may have to be confined to a hospital if the drug regimen is so complex that the patient may forget to consume one pill and thereby possibly cause death or serious bodily injury. As such, due to complex pharmaceutical regimens, some patients must become hospitalized to ensure their survival.

[0006] Accordingly, there is a need for a method and/or device for aiding patients to remain compliant with a pharmaceutical regimen.

BRIEF SUMMARY OF THE INVENTION

[0007] In accordance with an embodiment of the present invention, a method is provided which aids patient in remaining compliant with a complex pharmaceutical regimen. The method discussed in the detailed description of the invention includes the following steps: reviewing a pharmaceutical regimen of a patient, providing the patient with a quantity of medication dispensers, tracking the quantity of the medication dispensers, contacting a prescribing doctor to obtain authorization to refill additional medication dispensers, and delivering the refilled medication dispensers to the patient. The method and the medication dispenser within the method stated above, in particular, aids the patient in staying compliant with the pharmaceutical regimen. This is accomplished by improving the communication between the prescribing doctor and the pharmacist, simplifying the pharmaceutical regimen to the greatest extent possible, and presenting the pharmaceutical regimen in an organized fashion to the patient such that the pharmaceutical regimen is easily rememberable.

[0008] The communication between the prescribing doctor and the pharmacist may be improved through the use of the method in conjunction with the medical dispenser, as discussed below and within the detailed description of the present invention. The medication dispenser aids in improving the communication between the prescribing doctor and the pharmacist by placing the complete pharmaceutical regimen of the patient on an indicia flap of the medication dispenser. In this way, both the pharmacist and the prescribing doctor may view the complete pharmaceutical regimen and determine whether the pharmaceutical

regimen of the patient contains any outdated drugs which have been replaced by new and improved pills. Additionally, the pharmacist may review the indicia flap to check for any adversely interacting pills within the pharmaceutical regimen. The above described adjustments to the pharmaceutical regimen may be accomplished by the pharmacist and/or the prescribing doctor.

[0009] As discussed above and in the detailed description of the present invention, the review may check for redundancy within the pharmaceutical regimen, for any adversely interacting pills within the pharmaceutical regimen, and among other things, a determination of whether the pharmaceutical regimen contains any outdated drugs which are no longer in use. These adjustments may help the patient to remain compliant with the pharmaceutical regimen in that the pharmaceutical regimen is simplified to the greatest extent. For example, if the pharmaceutical regimen contained three pills which had to be taken at various intervals throughout the day and throughout the week and through the review process one of the three pills was eliminated then the pharmaceutical regimen is made less complex.

[0010] The medical dispenser may have the indicia flap and a pill flap which are foldable on top of each other. When the indicia flap and the pill flap are placed in the open position, the indicia which may be located on the left side may have various printed matter such as a picture or sketch of the drug, drug information, indication (i.e., purpose of drug), directions, and warnings. The pill flap when the medication dispenser is in the open position reveals a plurality of compartments which are arranged by the day of the week and various times of the day. The pills which are indicated or identified on the indicia flap may be contained within the compartments. The pills contained within the compartments are appropriately placed therein such that consuming the pills contained in a specific compartment as to the day of week and time of day will place the patient in compliance with the pharmaceutical regimen. In this regard, the patient need not remember the various requirements in relation to the various pills within the pharmaceutical regimen because the compartments arranged on the pill flap as to the time of day and day of week indirectly instruct the patient as to the intervals at which the patient must consume the pills.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] An illustrative and presently preferred embodiment of the invention is shown in the accompanying drawings in which:

[0012] Figure 1 is a flow chart of a method of aiding patients remain compliant with a pharmaceutical regimen and includes use of a medication dispenser which may organize a complex pharmaceutical regimen to the patient in an easily rememberable manner and may be used to communicate the pharmaceutical regimen between a pharmacist and prescribing doctors;

[0013] Figure 2 is the medication dispenser of Figure 1 in an unassembled perspective view and illustrates a summary of the pharmaceutical regimen on an indicia flap which may provide instructions to a clerk filling medication dispenser compartments;

[0014] Figure 3 is the medication dispenser of Figure 1 in an assembled perspective view and illustrates pills that are contained in compartments may be readily identifiable by quick reference to an indicia flap; and

[0015] Figure 4 is a front view of the medication dispenser in a closed position.

DETAILED DESCRIPTION OF THE INVENTION

[0016] The drawings referred to herein are for the purpose of illustrating the preferred embodiments of the present invention and not for the purpose of limiting the same. Specifically, Figure 1 illustrates a medication compliance and management method which includes step 10 of reviewing a pharmaceutical regimen of a patient, step 20 of providing the patient with a medication dispenser in accordance with the reviewed pharmaceutical regimen, step 30 of tracking a quantity of medication dispensers 100, step 40 of contacting a prescribing doctor to obtain authorization to refill additional medication dispensers 100, and step 50 of delivering the refilled medication dispenser 100 to the patient.

[0017] In the reviewing step 10, unless the context otherwise requires or suggests, the pharmaceutical regimen may be a requirement placed on patients to consume pills 102 in a particular manner. For example, the pharmaceutical regimen may be a requirement that the patient consume a first pill 102 three times a day, seven days a week, and a second pill 102 two times a day, every other day. Additionally, the pharmaceutical regimen may refer to the actual pills.

[0018] The reviewing step 10 may be an optional step in the method stated above but the reviewing step 10 is preferable based on the following purposes of the reviewing step which are only representative and not inclusive of all the purposes which may be accomplished during the review of the pharmaceutical regimen. The review process may be for the purpose of eliminating redundancy within the pharmaceutical regimen. The review may be performed to determine whether there are any interactions between the prescribed pills 102 which may adversely interact with each other. In this regard, the review may determine whether some of the pills 102 should and may be taken at different intervals from adversely interacting pills 102. The review may additionally be performed to determine whether there are other alternative pills 102 which may either be less expensive or a better alternative so as to benefit the patient monetarily and/or in terms of the patient's health. Moreover, the review may accomplish the purpose of determining whether some of the pills 102 are outdated and have other better alternatives on the pharmaceutical market. The review process ultimately may benefit the patient because the review process may eliminate pills from the pharmaceutical regimen and thereby simplify the pharmaceutical regimen such that the patient is more likely to remain compliant with their pharmaceutical regimen.

[0019] The review process in view of its purposes becomes increasingly important as the pharmaceutical regimen becomes more complex. A complex pharmaceutical regimen may include a plurality of pills 102 with each pill 102 being taken at different times of the day and at different intervals during the week. The pharmaceutical regimen may be further complexified due to the chemical interactions between pills 102 within the pharmaceutical regimen which may require the patient to take the pills 102 in a certain sequence such as after a meal. In this regard, the review process may be crucial in reducing the complexity of the pharmaceutical regimen of the patient.

[0020] The pharmaceutical regimen of the patient may further be complexified as the patient ages. Oftentimes, the patient will consult with a doctor concerning health related issues of the patient. The doctor may prescribe medication as warranted by the health related issues of the patient. As discussed in the background of the invention, as a patient ages, additional health related issues arise and compound with prior existing health related issues. In this regard, generally, as patients age, the patient may be required to take an increasing amount of pills 102 to further complicate their current pharmaceutical regimen.

[0021] The pharmaceutical regimen of the patient may further be complexified because the patient may be under the care of a plurality of doctors. In this regard, the patient may obtain prescriptions by different doctors with prescriptions that are redundant or otherwise, obsolete. For example, especially, in today's age of doctor specialties such as ear, nose and throat doctors ("ENT doctors"), at times, the patient may be required to consume medication prescribed by both a general doctor and the specialist wherein the communication between the doctor and the specialist may be impaired. The impairment may be a result of the doctor having a different preferred medication to treat the same health related issue of the patient compared to the specialist. Furthermore, the time/cost constraints of the doctor and the specialist may impair the communication between the two doctors. The result of poor communication between the prescribing doctor(s) and pharmacist in addition to poor communication that may exist between the patient and prescribing doctor(s) may result in various errors in the overall pharmaceutical regimen of the patient. The various errors may include redundancy of pills 102 and inclusion of outdated pills 102 within the pharmaceutical regimen.

[0022] The review may be accomplished by a health care professional (HCP) such as the prescribing doctor but is preferably reviewed by the pharmacist given that the pharmacist may have more extensive training in pharmacology. There are additional problems if the prescribing doctor were to review the pharmaceutical regimen in that the doctor may not be reviewing the complete pharmaceutical regimen. As stated above, the prescribing doctor may be one of many prescribing doctors. For example, the prescribing doctor may be a general doctor. Apart from the general doctor, the patient may have been referred to a specialist such as an ENT specialist which the general doctor may not have knowledge about and may have prescribed other pills to the patient. In this regard, there may be a lack of communication between the various prescribing doctors. Unlike the various doctors which the patient might have to visit due to the nature of the patient's health issues, the prescriptions of the various doctors may be filled by a single pharmacist. In this regard, the pharmacist is preferably the one to review the pharmaceutical regimen.

[0023] Preferably, the complete pharmaceutical regimen is reviewed and not only a portion of the pharmaceutical regimen is reviewed. However, there may be a lack of centralized recording which prevents review of the complete pharmaceutical regimen. In this

regard, the complete pharmaceutical regimen may be obtained through various methods. One method is for the pharmacist to compile a list of medications which the patient has been taking throughout the years. In other words, each time that the patient visits the pharmacist to obtain a refill prescription or fill a new prescription, then the pharmacist may compile the list as the years progress. The compiled list may be stored such as in a computer such that the reviewing step 10 may be accomplished by any pharmacist with adequate training and expertise. This will also require that the patient fill the prescription with the same pharmacist or entity such as Millennium Care Pharmacy of Los Angeles, California throughout the years. Otherwise, the complete medication history of the patient may be unknown. In a second method, the complete pharmaceutical regimen may be obtained through the general doctor or a single doctor through which health related issues are communicated to. In a third method, the complete pharmaceutical regimen may be obtained directly from the patient. In this regard, the patient must be meticulous in recording their current pharmaceutical regimen and their prior medication history so as to be able to provide their complete pharmaceutical regimen history to the HCP. In a forth method, a medication dispenser as will be discussed below in detail in relation to step 20 of providing medication dispenser may be operative to assist the HCP in obtaining the complete pharmaceutical regimen for review.

[0024] The reviewing step 10 may be accomplished during different stages of the patient's life. The trigger which prompts a HCP such as a doctor or pharmacist to recommend to the patient that they should have their pharmaceutical regimen reviewed may be from a serious life threatening event. For example, at certain times in a patient's life, the patient may be in an accident or undergo major surgery which requires the patient to consume a plurality of pills 102 after the accident or surgery. In this situation, the reviewing step 10 may be accomplished after the surgery or accident. At other times in a patient's life, the trigger may be harder to determine such as when the patient's health slowly and increasingly deteriorates. In this instance, the reviewing step 10 may occur when the patient, doctor or pharmacist determines that the pharmaceutical regimen of the patient is too complex for the patient to comply with in the absence of a method or device to aid the patient to remain compliant with their pharmaceutical regimen. Moreover, the reviewing step 10 may be triggered in the normal course of the method, specifically, during steps 10, 20,30,40,50 within the method. For example, during the tracking step 30, when it has been

determined that the patient may not have a sufficient supply of medication dispensers 100. In another example, the reviewing step 10 may also be automatically triggered when the health care professional receives notification of negative information about a pill such as obsolescence. In this instance, the HCP who is typically in the health field may be notified of such recall or obsolescence may search in a database of patients to identify patients taking the recalled or obsolete pills. At this time, the HCP may review the pharmaceutical regimen of those patients. If the HCP determines that the pharmaceutical regimen should be adjusted then the HCP may either contact the pharmacist or prescribing doctor to request a change in the pharmaceutical regimen immediately, or notate the suggested change in the patient's file such that the suggestion may be approved at a later date and incorporated with the next shipment of medication dispensers 100.

[0025] The second step 20 includes providing the patient with at least one medication dispenser 100. The medication dispenser 100 may be filled with a plurality of pills 102 that make up the pharmaceutical regimen of the patient. The number of medication dispensers 102 provided to the patient may be a function of pharmaceutical review interval and/or the interval till the patient revisits the prescribing doctor(s) or other factors. For example, the pharmaceutical regimen may be reviewed quarterly. And, in this instance, the patient may be provided with three months supply of medication dispensers 100. However, if the patient's next appointment is within one month, then the patient may be provided with a one month supply of medication dispensers 100.

[0026] The medication dispenser 100 provided to the patient in step 20 may comprise a pill flap 104 and an indicia flap 106, as shown in Figure 2. The medication dispenser 100 may have an opened position, as illustrated in Figure 3, and a closed position as illustrated in Figure 4 with each position having a front and back side. The front open position is illustrated in Figure 3, and the front closed position is illustrated in Figure 4 as the top view thereof. The pill flap 104 may have formed thereon a plurality of compartments 108. The compartments 108 may be transparent from the front open position (see Figure 3) of the medication dispenser 100. Each compartment 108 may be sized and configured to receive the pills 102. For example, each compartment 108 may have a square or rectangular configuration. Each compartment may define a height 110 (see Figure 4). The size of the compartment 108 may be sized and configured into other shapes to receive pills 102 in

accordance with the pharmaceutical regimen. The plurality of pills 102 within each of the compartments 108 may be removed on a per compartment 108 basis. The removability of the pills 102 within the compartment 102 may be accomplished by manufacturing the compartment 108 with a thin flexible transparent plastic material such that pressing against the compartments 108 may release the pills 102 from the compartment 108. For example, the compartment 108 may be blister packed, and the compartment 108 may be pressed from the front open position (see Figure 3) such that the pills 102 contained therein would penetrate through a penetrable membrane 112 (see Figure 2) through a back layer 114 of the pill flap 104.

[0027] On both sides of a front layer 116 of the pill flap 104, printed indicia may indicate the time of day and day of week which the pill 102 should be consumed, as illustrated in Figures 2 and 3. The indicia may be aligned with respective compartments 108. For example, along the top of the pill flap 104, the following indicia may be printed: morning, afternoon, evening, and bedtime, and along the side of the pill flap 104, the following indicia may be printed: Sunday, Monday, Tuesday, Wednesday, Thursday, Friday, and Saturday. There may be a total of twenty eight compartments arranged in seven rows and four columns.

[0028] The back layer 114 may have a series of apertures 117 which are aligned with the compartments 108, and the back layer 114 may have the penetrable membrane 112 attached thereon through an adhesive such that the penetrable membrane 112 is interposed between the front and back layers 116,114 when they are folded on top of each other. A pressure adhesive or a heat activated adhesive may also be laid on the penetrable membrane 112 such that the front layer 116 may be attached to the back layer 114. The penetrable membrane 112 defines a portion of the compartment 108 and in this regard, the adhesives may be selectively placed on the penetrable membrane 112 such that the adhesive is not on the portion of the penetrable membrane 112 which partially defines the compartment 108. Additionally, the adhesive may not be placed on portions of the penetrable membrane 112 that may be exposed through the apertures 117. This is to avoid the pills 102 from sticking onto the adhesive when the patient attempts to remove the pills 102 from the compartment 108, and to avoid the penetrable member 112 exposed though the apertures 117 of the back layer 114 from adhering to dirt and other debris from the environment. A protective layer 118 may be placed on the adhesive located on the side of the penetrable membrane 112 which attaches to

the front layer 116 so as to protect the adhesive properties of the adhesive prior to filling the compartment 108 with respective pills 102. Prior to filling the compartments 108 with pills 102, the back and front layers 114, 116 are laid open, as shown in Figure 2. Then, the pills 102 are filled or inserted into respective compartments 108. During this filling or inserting of the pills into the compartments, the printed indicia on the indicia flap 106 may be useful to the person actually filling the compartments 108 with the various pills 102 in that the printed indicia provides an accurate and convenient reference to which the person may use to fill the compartments 108 to ensure that the proper pills 102 are being inserted into the proper compartments 108. The protective layer 118 may be removed and the back layer 114 may then be folded over the front layer 116. At this point, the front layer 116 may be attached to the back layer 114 such as through pressure or heat according to the type of adhesive.

[0029] The insertion of pills 102 within appropriate compartments 108 may be one means of improving communications between the patient, pharmacists, and/or doctor(s) in relation to the patient's pharmaceutical regimen. For example, instead of explaining in detail the consumption requirements of each individual pill 102 within the patient's pharmaceutical regimen, the consumption requirement of the aggregate of pills 102 may be organized and presented to the patient in an easy to remember format. In particular, the patient may be instructed to consume a certain group of pills 102 during the day and during the week as indicated on the pill flap 104. In this regard, the patient may be advised as to the consumption requirement of the aggregate of pills within the pharmaceutical regimen in addition to or rather than the consumption requirement of each individual pill 102. This may be a preferred mode of communication between the pharmacist and the patient in that a summary is easier to remember compared to the numerous facts in relation to each specific pill 102. Moreover, the patient may not be familiar with the technical terms of related to each pill 102 and may be confused as to the meaning of all the trade terms that the pharmacist may be using to instruct the patient in relation to a particular pill 102.

[0030] The pill flap 104 may have horizontal perforations 120 between each of the days of the week. This allows the patient to tear off each days prescription such that the patient does not need to carry the whole medication dispenser 100 but may carry only the days worth of pills 102 for that particular day.

[0031] The indicia flap 106 may have contained thereon printed matter in the form of a summary of the pharmaceutical regimen which may identify the pills 102 contained in the compartments 108, state the purposes of the pills 102 contained in the compartments 108, warn of possible interaction of the pills 102 with other pills 102, and state directions for consuming the pills 102. The identification may be by name and/or picture (e.g., black and white photograph, colored photograph, or sketch) of the pill 102 contained in the compartments 108. On the indicia flap 106, the patient may be instructed as to the pharmaceutical regimen with respect to each individual pill 102. The indicia flap 106 additionally helps patients to comply with the pharmaceutical regimen in that certain pills may have to be taken prior to or after a meal which may be indicated on the indicia flap 106. As such, the patient may remove from one compartment 108 a set of pills 102 and by referencing the indicia flap 106 may quickly determine the interactions of the various pill 102 and a sequence of consuming the pills 102 if a particular sequence is required. The printed picture or sketch of the various pills 102 allows the patient to identify which pills 102 are to be taken before a meal and after the meal after reading the directions on the indicia flap 106. The printed picture or sketch also allows the patient to ensure that the pills 102 within the medication dispenser 100 has been inserted into the proper compartments.

[0032] The medication dispenser 100 when in the closed position may have indicia printed thereon to notify or remind the patient of the place to call for refills, the prescribing doctor's contact information, the pharmacist's contact information, and/or the HCP's contact information. The medication dispenser 100 may have printed indicia thereon which also indicate the date the medication dispenser 100 was refilled.

[0033] The third step 30 stated above in this method of aiding patients to comply with the complex pharmaceutical regimen is the step 30 of tracking the quantity of medication dispensers 100 in the possession of the patient. As stated above, in providing step 20, the patient is provided with a quantity of medication dispensers 100. Behind the scenes, the plurality of medication dispensers 100 given to the patient may be tracked by a HCP such as a pharmacist, doctor or other organization. The medication dispenser 100 provides a quantity of pills 102 to the patient for a set period of time. The HCP may with the aid of a computer software track all patients within its system to determine when a particular patient's quantity of medication dispensers 100 are depleted or may soon become depleted.

[0034] The fourth step 40 in this method of the present invention is contacting the prescribing doctor to obtain authorization to refill the medication dispensers 100. This step may be triggered as a result of the third step 30 which is the step of tracking the quantity of filled medical dispensers 100 in the patient's possession. In particular, the software which may be used to track the quantity of medication dispenser 100 may automatically remind the HCP to contact the prescribing doctor to obtain authorization to refill the medication dispensers 100. For example, at set intervals such as every week or day, the computer may provide a list of patients who may need additional medication dispensers. The HCP may contact the prescribing doctor to obtain authorization. During this step, the HCP may further review the pharmaceutical regimen with the prescribing doctor. Upon authorization from the prescribing doctor, as stated in step 50, the HCP may deliver additional medication dispensers 100 to the patient either at their home or at another specified location.

[0035] Unless the context otherwise suggests or requires, the term pills 100 used herein refer to any medication either prescribed by the doctor, any medication that may be purchased over the counter, or any other type of medication. The term pill 102 used herein are for the purpose of illustrating various aspects of the present invention and not for the purpose of limiting the same. For example, the pill may be any drug or medication that may be inserted into the compartment of the medication dispenser.

[0036] This description of the various embodiments of the present invention is presented to illustrate the preferred embodiments of the present invention, and other inventive concepts may be otherwise variously embodied and employed. The appended claims are intended to be construed to include such variations except insofar as limited by the prior art.